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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,620

06/27/2007

Jonni Moore

P-7671-US

5253

49443 7590 06/11/2010
Pearl Cohen Zedek Latzer, LLP
1500 Broadway
12th Floor
New York, NY 10036

EXAMINER

MARTIN, PAUL C

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

06/11/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,620	Applicant(s) MOORE ET AL.	
	Examiner PAUL C. MARTIN	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,6,7,9-12 and 14-27 is/are pending in the application.
- 4a) Of the above claim(s) 14-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6,7, and 9-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 3, 6, 7, 9-12 and 14-27 are pending in this application, Claims 14-27 are acknowledged as withdrawn, Claims 1, 3, 6, 7 and 9-12 were examined on their merits.

The objection to the Drawings as failing to comply with 37 CFR 1.84(p)(5) because they include following reference character(s) not mentioned in the description has been withdrawn due to the Applicant's amendments to the Drawings filed 04/27/2010.

The objection to the Specification for the improper use of trademarks has been withdrawn due to the Applicant's amendments to the Specification filed 04/27/2010.

The objection to Claim 13 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the matter of a previous claim has been withdrawn due to the Applicant's cancellation of the claim in the amendments to the Claims filed 04/27/2010.

The rejection of Claims 1, 6 and 8 under 35 U.S.C. § 112, 1st paragraph, as failing to comply with the enablement requirement has been withdrawn due to the Applicant's cancellation of Claim 8 in the amendments to the Claims filed 04/27/2010.

Claim Objections

Claims 8 and 13 are newly objected to because of the following informalities:
Newly cancelled claims 8 and 13 should have the text of the claim deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 6, 7 and 9-12 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Fontenot *et al.* (2003) for reasons of record set forth in the prior action.

Response to Arguments

Applicant's arguments filed 04/27/2010 have been fully considered but they are not persuasive.

The Applicant argues that Fontenot *et al.* does not teach or suggest the claimed feature of “determining beryllium sensitivity...comprising staining a peripheral blood leukocyte (PBL)...with...CFSE.” Applicant alleges that Fontenot *et al.* relates to labeling sorted (separated) bronchoalveolar lavage (BAL) CD+4 T-cells with CFSE and that biologic responses in separated cell populations frequently differ from those in a native unseparated environment and thus the responses of the unseparated CD+4 T-cells in the BAL may differ from unseparated CD+4 T-cells unexpectedly leading to a more robust and relevant diagnostic marker (Remarks, Pg. 12, Lines 6-17).

This is not found to be persuasive for the following reasons, as discussed in the prior action, Fontenot *et al.* teaches a method wherein peripheral blood mononuclear cells (PBMCs) and bronchoalveolar lavage (BAL) cells from subjects diagnosed with chronic beryllium disease (CBD) are stained with monoclonal antibodies to CD4, CD8 and CD28 in order to identify the lymphocyte (T-cell) population and contacting the identified BAL T-cell subpopulation with the intracellular protein stain CFSE. PBMCs consist of any blood cell having a round nucleus, for example, monocytes and lymphocytes. All white blood cells (e.g. monocytes and lymphocytes) are by definition, leukocytes.

Therefore, Fontenot *et al.* teaches the isolation of both PBL and BAL T-cell populations. As discussed in the Prior Action, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Fontenot *et al.* wherein BAL T-Cells are stained with CFSE in order to measure proliferation due to exposure to beryllium by substituting PBL T-cells (or PBMCs) for BAL cells because the reference teaches the use of both types of cells in beryllium exposure assays and one of ordinary skill in the art would have recognized that the cell types were art-recognized equivalents. The MPEP states:

In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. *In re Ruff*, 256 F.2d 590, 118 USPQ 340 (CCPA 1958)

In response to applicant's argument that biologic responses in separated cell populations frequently differ from those in a native unseparated environment and thus the responses of the unseparated CD+4 T-cells in the BAL may differ from unseparated CD+4 T-cells unexpectedly leading to a more robust and relevant diagnostic marker, the Examiner notes that the comprising language of the claim does not limit the procedure to either separated or non-separated cells. The allegation of a more "robust" or relevant diagnostic marker is unsubstantiated by any evidentiary support and is merely the opinion of counsel. The MPEP states:

The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

The Applicant argues that the Examiner without any factual data or support, merely asserts that one can substitute PBL T-cells for BAL cells and that the reference's purpose was to determine how the function of BAL cells was impaired by decreased CD28. Applicant asserts that therefore the purpose of the reference was not to determine if there was a predictive response of PBMC to beryllium as measured by CFSE and that additionally the reference did not use CD3 but instead used CD4 and CD28, therefore the cells measured included monocytes and not necessarily T-cells (Remarks, Pg. 12, Lines 18-22 and Pg. 13, Lines 1-9).

This is not found to be persuasive for the following reasons, as stated above and in the prior action, the Examiner provided reasoned, logical statements as to why one of ordinary skill in the art would find it obvious and desirable to substitute PBMC lymphocytes for BAL derived lymphocytes. In response to applicant's argument that the purpose of the reference was not to determine if there was a predictive response of PBMC to beryllium as measured by CFSE, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The argument that the reference used CD4 and not CD3 markers is not found to be persuasive as the claims specify that the cell surface marker can be CD3, CD4 or a combination thereof.

Conclusion

No Claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL C. MARTIN whose telephone number is (571)272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1657

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

06/09/2010

/Rebecca E. Prouty/
Primary Examiner,
Art Unit 1652